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JCO6 Rec'd PCT/PTO 27 MAY 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#3

Atty. Docket: SUGIMURA=4

In re Application of:	)	Confirmation No.:
	)	
Kazuhisa SUGIMURA et al	)	Art Unit:
	)	
Appln. No.: 10/526,072 ✓	)	Examiner:
	)	
Filed: February 28, 2005	)	Washington, D.C.
371(c) Date: 8/28/2003	)	
	)	
For: HUMAN ANTI-HUMAN	)	May 27, 2005
INTERLEUKIN-6 ANTIBODY	)	
AND FRAGMENT...	)	

**INFORMATION DISCLOSURE STATEMENT [IDS]**

Customer Service Window, Mail Stop Amendment  
Honorable Commissioner for Patents  
U.S. Patent and Trademark Office  
Randolph Building  
401 Dulany Street  
Alexandria, Virginia 22314

Sir:

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application; and before the mailing date of a first office action on the merits.

2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., form BN/SB/08A/B) of all patents, publications, or other information submitted for consideration

by the office, either incorporated into this IDS or as an attachment hereto. Other than U.S. patent(s) and/or published U.S. application(s), which 37 CFR §1.98(a)(2)(ii) does not require to be filed unless specifically required by the Office, a copy of each document listed is attached.

3. Document AA is not in the English language. In accordance with 37 CFR §1.98(a)(3), Applicant states:

[X] A concise explanation of the relevance of Document AA can be found on page 4 of the specification.

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

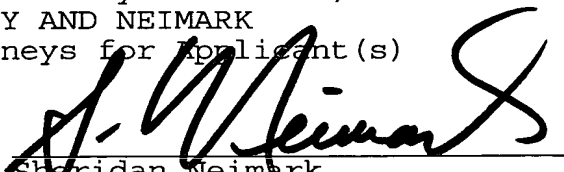
5. Other information being provided for the examiner's consideration follows:

*A copy of the International search report is attached.*

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in 37 CFR §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,  
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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

Application Number	10/526,072
Filing Date	February 28, 2005
First Named Inventor	K. SUGIMURA et al
Group Art Unit	
Examiner Name	
Attorney Docket Number	SUGIMURA=4

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AA	Dictionary of Immunology, 1 <sup>st</sup> edition, page 49, 1993 (2 <sup>nd</sup> edition, page 60).	
	AB	S. AKIRA et al; "Interleukin-6 in Biology and Medicine"; <i>Advances in Immunology</i> , Vol. 54, pages 1-78; 1993.	
	AC	R. GEJIMA et al; "Human Single-chain Fv (scFv) Antibody Specific to Human IL-6 with the Inhibitory Activity on IL-6-signaling"; <i>Human Antibodies</i> ; Vol. 11(4), pages 121-129; 2002.	
	AD	T. HIRANO et al; "Interleukin-6: Possible Implications in Human Diseases"; <i>Res. Clin. Lab.</i> , Vol. 19(1), pp. 1-10; 1989.	
	AE	B. KREBS et al; "Recombinant Human Single Chain Fv Antibodies Recognizing Human Interleukin-6"; <i>The Journal of Biological Chemistry</i> ; Vol. 273(5), pp. 2858-2865; 1998.	
	AF	J. D. MARKS et al; "By-passing Immunization Human Antibodies from V-gene Libraries Displayed on Phage "; <i>Journal Molecular Biology</i> ; Vol. 222(3); pp. 581-597; 1991.	
	AG	M. MIHARA et al; "Interleukin-6 (IL-6) Induces the proliferation of Synovial Fibroblastic Cells in the Presence of Soluble IL-6 Receptor; <i>British Journal of Rheumatology</i> "; Vol. 34(4); pp. 321-325; 1995.	
	AH	M. MIHARA et al; "Humanized Antibody to Human Interleukin-6 Receptor Inhibits the Development of Collagen Arthritis in Cynomolgus Monkeys"; <i>Clinical Immunology</i> ; Vol. 98(3); pp. 319-326; 2001.	
	AI	S. MONIER et al; "Growth Factor Activity of IL-6 in the Synovial fluid of patients with rheumatoid arthritis"; <i>Clinical and Experimental Rheumatology</i> ; Vol. 12(6); pp. 595-602, 1994.	
	AJ	F. MONTERO-JULIAN et al; "Pharmacokinetic Study of Anti-Interleukin-6 (IL-6) Therapy with Monoclonal Antibodies: Enhancement of IL-6 Clearance by Cocktails of Anti-IL-6 Antibodies"; <i>Blood</i> ; Vol. 85; pp. 917-924; 1995.	
	AK	N. NISHIMOTO et al; "Clinical Application of Interleukin-6 receptor antibody"; <i>Japanese Society for Immunology</i> ; Vol. 20 (2); pp. 87-94; 1997.	
	AL	A. OGATA et al; "Advances in Interleukin-6 Therapy"; <i>Clinical Pathology</i> ; Vol. 47(4); pp. 321-326, 1999.	

Examiner  
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Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2

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	AM	K. SATO et al; "Humanization of an anti-human IL-6 mouse monoclonal antibody glycosylated in its heavy chain variable region"; <i>Human Antibody Hybridomas</i> ; Vol. 7(4), pp. 175-193; 1996.	
	AN	D. WENDLING et al; "Treatment of Severe Rheumatoid Arthritis by anti-interleukin 6 monoclonal antibody"; <i>Journal Rheumatology</i> ; Vol. 20(2); pp. 259-262; 1993.	
	AO	J. WIJDENES et al "Human Recombinant Dimeric IL-6 Binds to Its Receptor as Detected by Anti-IL-6 Monoclonal Antibodies"; <i>Molecular Immunology</i> ; Vol. 28(11), pages 1183-1192; 1991.	
	AP	G. VREUGDENHIL et al; "Anaemia of chronic disease in rheumatoid arthritis"; <i>Rheumatol Int.</i> , Vol. 10 (3), pp. 127-130; 1990.	

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Considered

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.